

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

NOVARTIS PHARMACEUTICALS
CORPORATION,

Plaintiff,

v.
ACTAVIS LLC, et al.

Defendants.

C.A. No. 2:13-cv-1028-SDW-MCA

**DEFENDANTS WOCKHARDT USA LLC AND WOCKHARDT LTD.'S
REPLY MEMORANDUM IN SUPPORT OF THEIR MOTION TO
DISMISS COUNT II OF THE CORRECTED AMENDED COMPLAINT**

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Defendants Wockhardt USA LLC and Wockhardt Ltd. (collectively, “Wockhardt”) respectfully submit this reply brief in support of their Motion to Dismiss Count II of the Corrected Amended Complaint.

I. INTRODUCTION

Novartis sued Wockhardt on U.S. Patent No. 8,052,987 (“the ’987 patent”) in Count II of the 2012 Case, reviewed Wockhardt’s non-infringement position, and *chose not* to assert any claims of that patent against Wockhardt.¹ ***Not a single material fact regarding Wockhardt has changed since then.*** Novartis should not be allowed to keep filing lawsuits every time it makes a litigation decision that it later regrets. To be clear, Count II of the 2013 Case against Wockhardt is merely a do-over of Count II of the 2012 Case, and therefore, Wockhardt’s Motion to Dismiss should be granted.

Now, in its opposition, Novartis claims that Count II of the 2013 Case and Count II of the 2012 Case are materially different for three reasons: (1) the 2013 case involves additional parties; (2) the 2013 case involves different facts; and (3) the 2013 case involves different damages issues. (*See* 2013 Case, D.I. 232, Opp’n Br. at 1). ***Novartis is wrong on all three counts.***

¹ Civil Action No. 12-cv-3967-SDW-MCA is referred to herein as the 2012 Case. Civil Action No. 13-cv-1028-SDW-MCA is referred to herein as the 2013 Case.

First, the addition of new parties is irrelevant to Wockhardt. The issue is whether the dispute between Wockhardt and Novartis is duplicative. The fact that Novartis now has patent disputes regarding the '987 patent with additional defendants has no effect on the duplicity of Count II between Wockhardt and Novartis.

Second, contrary to Novartis's assertions, the facts in Count II of the 2013 Case are not different from Count II of the 2012 Case. In both cases, Novartis alleges the same injury (infringement), based on the same statutes (35 U.S.C. § 271(e), (b), and (c)), and seeks the same relief (injunctive relief and damages upon launch).

Finally, the damages issue has not changed. In the 2012 Case, Novartis alleged damages in the event that Wockhardt launched its generic Reclast product. In the 2013 Case, Novartis is still alleging damages upon launch of Wockhardt's generic Reclast product. Because Count II of the 2013 Case and Count II of the 2012 Case are in fact duplicative, Novartis is not entitled to continue this vexatious litigation.

Novartis also alleges that dismissal would only delay the inevitable. However, Novartis affirmatively waived its right to assert the '987 patent against Wockhardt. The waiver was made in the 2012 Case, a case that included claims for damages in the event that Wockhardt launched. Novartis has fully waived its

right to assert the '987 patent against Wockhardt by alleging infringement and then affirmatively choosing not to assert any claims from that patent.

II. ARGUMENT

A. Count II of the 2013 Case is Duplicative of Count II of the 2012 Case

Novartis attempts to downplay the harm skirting this Court's Local Patent Rules would cause by creating artificial differences between Count II of the 2012 Case and Count II of the 2013 Case. Novartis relies heavily on *Curtis v. Citibank, N.A.*, 226 F.3d 133 (2d Cir. 2000). While Novartis is correct that *Curtis* found that claims arising after the filing of the first complaint were improperly dismissed, Novartis ignores that the *Curtis* court also held that those claims that did not arise after the filing of the complaint were properly dismissed. *See Curtis*, 226 F.3d at 140. Because Count II of the 2013 Case is not actually based on facts arising after the filing of the Complaint, Novartis has applied the wrong findings of *Curtis*. The finding of *Curtis* applicable to this case states that where claims in the second case "aris[e] out of the same events as those alleged in [the first case]" it is not an abuse of discretion to dismiss the claims which could have been heard if timely raised. *Curtis*, 226 F.3d at 140. Novartis, like the Plaintiffs in *Curtis*, is "attempt[ing] to avoid the consequences" of its litigation choices. *Id.* And it is appropriate for this Court to prevent Novartis from doing so. *See id.*

A party has “no right to maintain two separate actions involving the same subject matter at the same time in the same Court and against the same defendant.” *Walton v. Eaton Corp.*, 563 F.2d 66, 70 (3d Cir. 1977). Because Count II of the 2013 Case is a separate action involving the same subject matter, at the same time against the same defendant, as Count II of the 2012 Case, Count II should be dismissed as to Wockhardt.

1. The Additional Parties in the 2013 Case are Irrelevant

Novartis first attempts to differentiate Count II of the 2013 Case and Count II of the 2012 Case by pointing to the additional defendants that it has elected to sue. However, Novartis’s decision to file suit against other defendants has no impact on whether or not the re-assertion of Count II against Wockhardt in the 2013 Case is duplicative of the assertion of Count II against Wockhardt in the 2012 Case. The suggestion that Novartis’s intent to press its claims against other defendants somehow warrants this Court forcing Wockhardt to participate in duplicative litigation is preposterous. While fostering judicial economy may be one aspect of the claim splitting doctrine, it is not the sole focus as Novartis suggests. Rather, “[t]he doctrine is also meant to protect parties from the vexation of concurrent litigation over the same subject matter.” *Curtis*, 226 F.3d at 138 (quoting *Adam v. Jacobs*, 950 F.2d 89, 93 (2d Cir. 1991)). When viewing the whole purpose of the claim splitting doctrine, it is apparent that dismissal of Count

II as to Wockhardt not only fosters judicial economy (by removing a litigant), but also protects Wockhardt from being forced to engage in unnecessary litigation over a duplicative claim.

2. The Theory of Liability Has Not Changed

Novartis attempts to paint Count II of the 2013 Case as a “new” claim, based on Novartis’s assertion of a “sham label.” However, this alleged “sham label” theory is nothing more than Novartis’s attorney argument in support of its induced infringement and contributory infringement claims. The truth is that nothing has changed. On the contrary, both of these causes of action were already asserted in Count II of the 2012 Case. (*See* 2012 Case, D.I. 1, Complaint at ¶ 46).

In both the 2012 Case and the 2013 Case Novartis alleged that Wockhardt’s submission of ANDA No. 203070 was an act of infringement under 35 U.S.C. § 271(e)(2)(A). (*See* 2012 Case, D.I. 1, Complaint, at ¶ 45; 2013 Case, D.I. 134, Corrected Amended Complaint, at ¶ 82). Both complaints also alleged contributory and induced infringement, upon sale of Wockhardt’s proposed generic product. (*See* 2012 Case, D.I. 1, Complaint, at ¶ 46; 2013 Case, D.I. 134, Corrected Amended Complaint, at ¶¶ 83-84). Moreover, the facts underlying Novartis’s allegations have not changed. For example, the series of events underlying the claims of induced or contributory infringement are identical. Novartis is still arguing that Wockhardt will infringe the ’987 patent by providing

its generic Reclast product to a doctor, and that the administration of such product by the doctor to treat osteoporosis will infringe the '987 patent. That series of events has not changed. These allegations of induced and contributory infringement were made in both Count II of the 2012 Case and Count II of the 2013 Case. Had Novartis not waived its ability to assert any claims from the '987 patent in the 2012 Case, Novartis would have been capable of pursuing infringement claims, including induced infringement and contributory infringement claims, in the 2012 Case.

Each of the issues that Novartis points to as allegedly “new issues” are merely sub-issues related to the allegations of induced and contributory infringement; allegations that Novartis not only could, but actually did, make in Count II of the 2012 Case. Contrary to Novartis’s claims, the operative events at issue (i.e. filing the ANDA) occurred well before the filing of the complaint. Moreover, the alleged induced and contributory infringement still has not happened. Accordingly, the operative event must be Novartis’s ability to allege induced and contributory infringement. As induced and contributory infringement were alleged in the 2012 Complaint, the operative event clearly did not occur “well after the date of the first complaint.” (*See* 2013 Case, D.I. 232, Novartis’s Opp’n Br. at 10-11).

Moreover, Novartis has already admitted to claim splitting, stating that it “has no desire to maintain separate suits against Wockhardt on the same issues . . . Novartis included the ’987 Patent in [the 2013 Case] against Wockhardt because of the ambiguity presented by Wockhardt’s intention to oppose Novartis’s proposed amendment to its Disclosure of Asserted Claims to add claims from the ’987 patent.” (2013 Case, D. I. 78 at 15); *see Katz v. Gerardi*, 655 F.3d 1212, 1219 (10th Cir. 2011) (finding that Plaintiff has essentially admitted to claim splitting by stating that it brought the second suit “to preserve the claims of the [investors in the new units] in the event that the relief sought from the Tenth Circuit . . . is not granted.”).

Because Novartis could, and did raise the same allegations, seeking the same relief in the 2012 Case as in the 2013 Case, Count II of the 2013 Case is duplicative of Count II of the 2012 Case and should be dismissed.

3. The Damages Issues Have Not Changed

Novartis next attempts to differentiate the cases by pointing to damages. However, the alleged change in damages in the 2013 Case is irrelevant to the case against Wockhardt. Novartis argues that a new suit was necessary to include all of the parties who have launched generic zoledronic acid products. But, when the 2013 Complaint was filed, no defendant had launched yet. (*See Confoy Decl. Ex. 1*). Instead, Count II of the 2013 Case included multiple new defendants who had

yet to launch. Similarly, in both Count II of the 2012 Case and Count II of the 2013 Case Novartis seeks injunctive relief and damages *if* Wockhardt engages in the commercial manufacture, use, offers to sell, sells or imports a generic Reclast product. (*See* 2012 Case, D.I. 1, Complaint, Prayer for Relief at ¶¶ 5 and 7; 2013 Case, D.I. 134, Corrected Amended Complaint; Prayer for Relief at ¶¶ 3-4).

Novartis's heavy reliance on the argument that it "could not" claim damages when the 2012 Case was filed is misplaced. In both cases Novartis did just that. Accordingly, because both Count II of the 2013 Case and Count II of the 2012 Case seek damages based on a future launch by Wockhardt, there has been no change in the allegations of damages as to Wockhardt.

Novartis affirmatively chose not to assert any claims from the '987 patent. Novartis cannot escape its litigation decisions by continually re-asserting duplicative claims from the 2012 Case.

B. Novartis Has Failed to Show Good Cause to Amend Its Disclosure of Asserted Claims in the 2012 Case and Is Precluded From Re-Asserting Duplicative Claims in Subsequent Cases

The crux of this issue is Novartis's attempts to avoid this Court's Local Patent Rules by re-asserting the '987 patent in a new case. Perhaps because Novartis regrets its failure to assert any claims of the '987 patent, thereby waiving its ability to assert that patent against Wockhardt in the 2012 case, it has been especially desperate to re-assert the '987 patent in the 2013 Case. However,

Novartis's change in litigation strategy does not warrant bypassing the Local Patent Rules.

1. Novartis Cannot Show Good Cause to Amend its Disclosure of Asserted Claims

On October 12, 2012, Novartis was required to disclose the claims that it would pursue in the 2012 Case. On that day, Novartis was aware of Wockhardt's non-infringement position, Novartis was aware that U.S. Patent No. 8,324,189 ("the '189 patent") had been allowed, and Novartis was aware of the upcoming expiration of its compound patent. With full knowledge of each of these facts, Novartis elected not to pursue any claims from the '987 patent against Wockhardt. (*See* 2013 Case D.I. 146-3, Disclosure of Asserted Claims).

More recently, Novartis has shifted its litigation strategy and is now attempting to revive the '987 patent in the 2012 Case. In support of its shift, Novartis relies on only one argument of good cause -- a change in business circumstances based on the issuance of the '189 patent. (*See* 2012 Case, D.I. 51). However, this Court has already rejected the basis of Novartis's good cause argument, explaining that:

[I]t strains credibility in my opinion, quite frankly, to say that it was only at the time that this '189 patent came around that we realized we can do anything [on the '987 patent]. ***That just doesn't make sense to me.*** And I don't think it's supported by the record. I don't think the dates support that. I think that's very clear.

(2013 Case, D.I. 131, Mar. 1, 2013 Hearing Tr. 76:23-77:3 (emphasis added)). Because Novartis cannot show “good cause” for its proposed amendment, it will be unable to amend its Disclosure of Asserted Claims.

2. The Re-Assertion of the ’987 Patent is Precluded

Because Novartis cannot show good cause to amend its Asserted Claims, the only way to revive the ’987 patent against Wockhardt is to bypass this Court’s Local Patent Rules. Novartis has already admitted that the re-assertion of the ’987 patent was an end around of the Local Patent Rules, stating that it “included the ’987 Patent in [the 2013 Case] against Wockhardt because of the ambiguity presented by Wockhardt’s intention to oppose Novartis’s proposed amendment to its Disclosure of Asserted Claims to add claims from the ’987 patent.” (2013 Case, D.I. 78 at 15).

Novartis fails to address the fact that allowing the reassertion of the ’987 patent in a new case, based on the same facts, would annihilate the purpose of the Local Patent Rules by allowing Plaintiffs to re-assert the ’987 patent even if this Court finds that there is no good cause to amend. Rather, Novartis attempts to side-step the issue by arguing that this harm is irrelevant because Novartis could re-assert the ’987 patent even if the motion to amend is denied. This argument is wrong. First, Novartis attempts to correlate its position to *Frolow v. Wilson Sporting Goods Co.*, 710 F.3d 1303 (Fed. Cir. 2013). Novartis ignores a

significant difference; *Frolow* denied a party the right to assert, for the first time, certain products. *See Frolow*, 710 F.3d at 1307. Novartis, on the other hand, asserted the '987 patent, then essentially withdrew it after Wockhardt provided its non-infringement position.

Novartis also attempts to avoid the Local Patent Rule problem by suggesting that a dismissal of the '987 patent in the first case would have no preclusive effect, but this argument falls short. Novartis's argument improperly limits the scope of *Curtis*. *Curtis*'s statements limiting the preclusive effect of the denial of a motion to amend were aimed only at those claims arising after the filing of a complaint. *See Curtis*, 226 F.3d at 139. As explained in detail above, Novartis has not raised new claims. Rather any claims for damages (upon sales) and infringement (direct, induced and contributory) could have been, and in fact, were raised in the 2012 Case. (*See* 2012 Case, D.I. 1, Complaint at ¶¶ 45-46; Prayer for Relief at ¶7).

For the same reasons, Novartis's argument that dismissal would be "pointless and counter-productive" must fail. Upon reaching a final judgment on the merits in the 2012 Case, Novartis will be precluded from filing a third suit based on Wockhardt's actual sales. *See Huck ex rel. Sea Air Shuttle Corp. v. Dawson*, 106 F.3d 45, 49 (3d Cir. 1997) (holding res judicata barred assertion of claims in second suit where claims could have been properly raised and litigated by plaintiff in first suit but were not and plaintiff's motion to amend complaint in first

suit to include those claims was denied); *Nilsen v. Moss Point*, 701 F.2d 556, 560, 563 (5th Cir. 1983) (“[R]es judicata . . . bars all claims that were or could have been advanced in support of the cause of action on the occasion of its former adjudication” and “theories which were the subject of an untimely motion to amend, filed in the earlier action, ‘could have been brought’ there.”); Restatement (Second) of Judgments § 25 comment b (“It is immaterial that the plaintiff in the first action sought to prove the acts relied on in the second action and was not permitted to do so because they were not alleged in the complaint and an application to amend the complaint came too late.”). Moreover, even if the 2012 Case had not yet reached a final judgment Novartis’s proposed third case would still be barred by claim splitting. *See Katz*, 655 F.3d at 1218 (“Thus, in the claim-splitting context, the appropriate inquiry is whether, assuming that the first suit were already final, the second suit could be precluded pursuant to claim preclusion.”).

Moreover, this theory is belied by Novartis’s own actions. Novartis filed its Corrected Amended Complaint in the 2013 Case on March 21, 2013. (*See* 2013 Case, D.I. 134, Corrected Amended Complaint). At that time, no defendant had launched a generic Reclast product. (*See* Confoy Decl. Ex. 1). Since March 21, 2013, at least three defendants have begun selling generic Reclast products. (*See* Confoy Decl. Ex. 2). However, Novartis has not filed new suits, and instead is

relying on its claims for damages “if defendants engage” in sales. (2013 Case, D.I. 134, Corrected Amended Complaint, Prayer for Relief at ¶ 4). The fact that Novartis has not needed to file a new complaint as each defendant in the 2013 Case has begun selling generic products is evidence that the allegations of damages “if Wockhardt engages in” sales of generic Reclast are sufficient and thus render any new suit upon actual sales duplicative. (*See* 2012 Case, D.I. 1, Complaint, Prayer for Relief at ¶ 7).

Novartis’s attempts to avoid the effects of the Local Patent Rules are meritless, and the Motion to Amend the Disclosure of Asserted Claims and re-assertion of the ’987 patent in the 2013 Case following the tacit acknowledgement of Wockhardt’s non-infringement of the ’987 patent, are desperate attempts to revisit a litigation decision to which Novartis no longer wishes to be held. Wockhardt should not be forced to pay the price of Novartis shifting sands approach to this litigation.

C. Consolidation Does Not Solve the Claim-Splitting Problem

Novartis’s assertion that consolidation is the appropriate method for addressing the duplicative nature of Count II of the 2013 Case is incorrect.

Consolidation will be improper if Novartis’s motion to amend its disclosure of asserted claims is denied. Where, as here, consolidation would grant Novartis a greater right than it would be entitled to without, consolidation is improper. “The

adoption of an incorrect procedure . . . should not result in a greater right . . . than would have been available had the correct course of amending . . . been followed.” *Walton*, 563 F.2d at 71. If the motion to amend the asserted claims is denied, consolidation would improperly revive the ’987 patent in a case where Novartis had given up, based on its own choices and behavior, the right to assert it. Such an end-run around of the Local Patent Rules should not be allowed.

In addition, in the event that Novartis’s motion to amend the asserted claims in the 2012 Case is granted, consolidation is unnecessary as the ’987 patent would already be a part of the 2012 Case.

III. CONCLUSION

For the foregoing reasons, Wockhardt’s Motion to Dismiss Count II should be granted.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I served the attached **Defendants Wockhardt USA LLC and Wockhardt Ltd.’s Reply Memorandum in Support of Their Motion To Dismiss Count II of the Corrected Amended Complaint and its supporting declaration** on this date upon Plaintiff’s counsel via CM/ECF.

Dated: May 13, 2013

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